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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : O'Donnell et al.

Serial No. : 09/716,964

Cnfrm. No. : 2211

Filed : November 21, 2000

For : ENZYMES DERIVED FROM  
THERMOPHILIC ORGANISMS THAT  
FUNCTION AS A CHROMOSOMAL  
REPLICASE, PREPARATION AND USE  
THEREOF

Examiner:  
Unknown

Art Unit:  
1633

TECH CENTER 1600/2900

SEP 12 2002

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RESPONSE TO RESTRICTION REQUIREMENT

U.S. Patent and Trademark Office  
P.O. Box 2327  
Arlington, VA 22202

Dear Sir:

In response to the March 13, 2002, written restriction requirement, applicants hereby elect Group I (i.e. claims 1-15 and 49-56), B (encoding delta subunit of *Thermus thermophilus*) with traverse.

Firstly, applicants submit that the inventions of Groups I and II are related inventions, i.e., both relate to polymerase subunits that are capable of use together to form a clamp loader of a polymerase III enzyme. At page 5 of the outstanding office action, the U.S. Patent and Trademark Office ("PTO") states the appropriate test for determining relatedness (i.e., inventions not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (emphasis supplied, citing MPEP §§ 806.04 and 808.01)) yet ignores the test. Instead, the PTO simply asserts that the DNA molecules of Groups I and II "comprise chemically unrelated structure[s] capable of separate manufacture, use and effect." Applicants do not dispute that the DNA molecules of Groups I and II can be separately manufactured and separately used. However, the PTO has completely ignored the fact that such DNA molecules are capable of use together. Applicants have disclosed that those DNA molecules can be recombinantly expressed and used to assemble a clamp loader (see, e.g., page 56, line 28 to page 62, line 28, Examples 13 and 14, and Examples 19-21, 24-25, and 30). Thus, because the inventions of Groups I and II are capable of use together, they must be related and it is immaterial that they have different operation, function, or effect.

As noted in MPEP § 808.02, to support restriction between related inventions, “the examiner ... must show by appropriate explanation on of the following: (A) Separate classification thereof...; (B) A separate status in the art when they are classifiable together...; or (C) A different field of search...” (emphasis added). In this case, applicants respectfully submit that the PTO has failed to fulfill its obligation in demonstrating that these related inventions must be restricted. Specifically, the PTO has failed to demonstrate the inventions cannot be searched together without undue burden because—as noted by the PTO on page 2 of the outstanding office action—the search for both inventions would involve searching class 435, subclass 194. This class/subclass contains approximately 84 patents directed to polymerases or polymerase subunits and, moreover, this class is not limited to polymerases or polymerase subunits from any one particular class of organisms. Therefore, the search for the invention of Group I and the invention of Group II would be nearly, if not completely, co-extensive. Where the classification is the same and the field of search is the same, as is the case here, and there is no clear indication of separate future classification, as is the case here, no reasons exist for dividing among the related inventions. See id. Thus, the PTO has failed to carry its burden in establishing that these related inventions require restriction.

Secondly, the PTO has failed to identify claims 1 and 2 as generic linking claims. Both claims 1 and 2 are listed within the subject matter of Groups I and II. Therefore, claims 1 and 2 are linking claims which link together the subject matter of those groups. See, e.g., MPEP § 809.03 (indicating that a generic claim linking species claims, if allowed, acts to prevent restriction between inventions otherwise divisible). Claim 1 is a generic claim reciting an “isolated DNA molecule from a thermophilic bacterium...encoding a DNA polymerase III-type enzyme subunit” and claim 2 is a dependent subgeneric claim which defines the encoded DNA polymerase III-type enzyme subunit recited in claim 1 as a member of the Markush Group that includes: alpha, beta, tau, gamma, epsilon, delta, delta prime, and SSB subunits. Because both of claims 1 and 2 link together the inventions of Group I (limited to delta) and Group II (limited to delta prime), these claims should be designated as linking claims and treated in a manner consistent with MPEP § 809.

Thirdly, applicants respectfully submit that restriction between A-D (and E-H) is improper. Applicants have identified four species of delta and delta prime, all from thermophilic bacteria (e.g., *Thermus thermophilus*, *Aquifex aeolicus*, *Bacillus stearothermophilus*, and *Thermotoga maritima*). Despite the fact that the DNA molecules from different species are not identical and, therefore, represent distinct chemical structures, these DNA molecules are related in their production of functionally similar delta subunits or

functionally similar delta prime subunits, respectively, all of which operate to form a portion of a clamp loader in a DNA polymerase III enzyme. Because the various species are functionally related, applicants should be entitled to examination of the claimed genus of delta (or delta prime) subunits.

In this case, therefore, an election of species (as opposed to restriction) requirement is appropriate for purposes of limiting the initial scope of search and examination. Should the PTO withdraw the restriction requirement among the various delta subunits (i.e., A-D), applicants provisionally elect the delta subunit of *Thermus thermophilus*. Claims reading on the delta subunit of *Thermus thermophilus* are claims 1-3 and 7-9. (Should the PTO withdraw both the restriction between Groups I and II, and the restriction between A-D and E-H, applicants also provisionally elect the delta prime subunit of *Thermus thermophilus*. Claims reading on the delta prime subunit of *Thermus thermophilus* are claims 1, 2, 16, and 20-22.)

Finally, applicants note that the PTO has completely disregarded the other subgenuses recited in the Markush group of claim 2, notably the alpha, beta, tau, gamma, epsilon, and SSB subunits. For substantially the same reasons noted above with regard to the restriction as between Groups I and II, the search and examination of these subgenuses can also be conducted with substantially no greater burden.

In view of all of the foregoing, applicants respectfully submit that the restriction requirement should be withdrawn at least in part.

Respectfully submitted,

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